REMARKS

Claims 1, 4, 6-14 and 17-22 are currently pending in the above-identified application. Claims 2, 3, 15 and 16 have been canceled and claim 5 has been withdrawn as directed to a non-elected claim. Claims 1, 4, 14 and 17 have been amended; claim 1 has been amended to incorporate language from dependent claims 2 and 3, now canceled, and claim 14 has been amended to incorporate language from now canceled claims 15 and 16. Claims 4 and 17 have been amended to recite proper antecedent support and better clarify that the immune response is an antibody response which is elicited by the encoded antigen. No new matter has been added by these amendments.

Claim Objections

The Examiner has objected to claims 1, 6-14 and 18-22 as containing subject matter which was non-elected. Claims 1 and 14 have been amended to more distinctly refer to eliciting an "immune" response to the encoded antigen, rather than a physiological response. Thus, the objection to the claims is obviated.

Claim Rejections under 35 USC §112

Claims 4 and 17 are rejected under 35 USC §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that claims 4 and 17 are vague and indefinite in that the metes and bounds of an "immune response produces antibodies" are unclear.

As noted above, Applicants have amended claims 4 and 17 to more clearly refer to the immune response that is elicited to the encoded antigen, wherein the immune response is an antibody response. Thus, this basis for rejection has been obviated.

Claims 1, 6-14 and 18-22 stand rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the enablement requirement. According to the Office, while the specification is said to be enabling for the production of antibodies, it does not allegedly provide enablement for a method of producing a physiological response, such as a therapeutic immune response.

As noted above, independent claims 1 and 14 have been amended to more clearly indicate that the response elicited to the antigen encoded by the M-DNA is an immune response. As recognized on page 7 of the Office action, Applicants have demonstrated the teachings of the instant specification by injecting M-DNA that encodes an antigenic protein into an animal, and Applicants demonstrated a specific immune response to the encoded antigen in the treated animal. The immune response was exemplified by detecting the presence of specific antibodies to the encoded antigen.

An antibody response to an antigen encoded by the M-DNA is evidence the specification enables compositions and methods for eliciting a specific immune response. An antibody response as shown by Applicants to a specific encoded antigen is proof that the components of acquired immunity are activated by the present invention. These include both humoral and cell-mediated components. For example, antigen presenting cells (APCs) such as dendritic cells take up the antigen, process it, and present it to an antigen-specific receptor on T cells, such as T helper cells (T_H). T_H cells are then stimulated to proliferate and release cytokines that provide various activation signals for the B cells. Antigen-specific B cells recognize the antigen via surface receptors and in the presence of the T-cell-secreted cytokines the B cells proliferate and then differentiate to produce the specific antibody that binds the encoded antigen.

Thus, Applicants have shown a response to a M-DNA encoded antigen, one that involves an interaction of cellular and soluble components of the immune system. The intracellular events that follow activation of the antigen-specific receptor by antigen are very similar in both B and T cells following receptor triggering at the cell surface. As a result of antigenic stimulation, both B and T cells differentiate into specific effector cells.

Having demonstrated this antigen-specific response, by the detection of antibodies, one of skill would appreciate that a wide variety of other antigen-specific immune responses are enabled by the present specification, depending, for example, on the antigen that is encoded by the DNA of the M-DNA complex. Thus, Applicants believe the full scope of the present claims is enabled by the specification and respectfully request reconsideration of this basis of rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: May 31, 2005

By: Steven W. Parmelee
Steven W. Parmelee
Reg. No. 31,990

TOWNSEND and TOWNSEND and CREW, LLP
Two Embarcadero Center, 8th Floor
San Francisco, CA 94111
Telephone: (206) 467-9600
Telefax: (415) 576-0300